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SECTION 9
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, SaiNath Intellectual Properties, LLC is required to submit with this Premarket Notification "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." SaiNath Intellectual Properties, LLC choose to submit a summary of information respecting safety and effectiveness.

Common/Usual Name:	Tube, Gastro-Enterostomy
Trade Name:	IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit
Classification Name:	78 KNT Gastrointestinal Tube & Accessories
CFR Reference:	21 CFR §876.5980, Class II
Classification Panel:	Gastroenterology/Urology
Submitter Name:	SaiNath Intellectual Properties, LLC 9438 Pebble Beach Ct. West Seminole, FL 33777
Contact Person:	I.V.S. Nath

INDICATIONS FOR USE

The IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit is indicated for use in percutaneous placement of a gastrostomy tube for feeding and/or medication in conjunction with an established gastrostomy tract, or using a Stamm Procedure. The gastrostomy tube may also be used for gastric decompression.

CONTRAINDICATIONS

Contraindications for this device are those specific to patients where evidence of granulation tissue, infection or stoma irritation are present. The product must NEVER be used in the vasculature.

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POTENTIAL COMPLICATIONS

Complications may include, but are not limited to minor wound infections at stoma site; leakage of gastric contents; gastrocolic fistula; and sepsis.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

SaiNath Intellectual Properties, LLC believes that the IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit is substantially equivalent to the currently marketed Bard® Dilation Kit with Tri-Funnel Gastrostomy Tube and Kimberly-Clark* Introducer Kit. Figure 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

The components of the IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit has the same characteristics as those devices that are currently marketed. There is no change in the performance characteristics or intended use.

PACKAGING AND STERILIZATION

The IYUNNI™ 3ID Tri-funnel Gastrostomy Tube Kit will be packaged in a tray and sealed with a Tyvek lid. The IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization.

CONCLUSION

SaiNath Intellectual Properties, LLC believes that the I IYUNNI™ 3ID Tri-funnel Gastrostomy Tube Kit is substantially equivalent to the currently marketed devices. Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1, the IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit is equivalent in its indications for use, design, and materials.

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FIGURE 9-1: SIMILARITIES AND DIFFERENCES BETWEEN IYUNNI™ 3ID TRI-FUNNEL GASTROSTOMY TUBE KIT, BARD® DILATION KIT WITH TRI-FUNNEL GASTROSTOMY TUBE AND KIMBERLY-CLARK* INTRODUCER KIT

	IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit (This 510(K))	Bard® Dilation Kit with Tri-Funnel Gastrostomy Tube (K063118)	Kimberly-Clark* Introducer Kit (K080253)
USE			
Indications	Feeding, medication, gastric decompression	Feeding, medication, gastric decompression	Feeding, medication, gastric decompression
Route of Administration	Percutaneous	Percutaneous	Percutaneous
GASTROSTOMY TUBE			
KIT COMPONENTS			
IYUNNI™ Soft Tip Introducer Dilator	Yes	No	No
External Dilator	No	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SaiNath Intellectual Properties, LLC
% Christopher Paradies, Ph.D.
FOWLER WHITE BOGGS, P.A.
501 East Kennedy Blvd., Suite 1700
TAMPA FL 33602

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Re: K092049
Trade/Device Name: IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: September 24, 2009
Received: September 29, 2009

Dear Dr. Paradies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

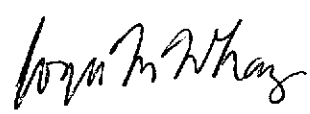
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Janine M. Morris, Director (Acting)
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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C. INDICATIONS FOR USE

510(k) Number (if known): ~~To Be Determined~~ K092049

Device Name: IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit

Indications for Use:

The IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit is indicated for use in percutaneous placement of a gastrostomy tube for feeding and/or medication using a Percutaneous Endoscopic Gastrostomy procedure. The gastrostomy tube may also be used for gastric decompression.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092049